K020594

MAR 8 2002

510(k) Summary of Safety and Effectiveness

Trade Name:	Diego Dissector and Drill System
Common Name:	Electrical Surgical Drill/Shaver
Classification Name:	Ear, Nose and Throat electric or pneumatic surgical drill (§ 874.4250)

Official Contact: Greg Sredin
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Date Prepared: February 21, 2002

The Diego Powered Dissector and Drill System's intended use is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures. Sinus applications would embody ethmoidectomy/sphenoethmoidectomy, polypectomy, septoplasty, and procedures such as the removal of septal spurs, antrostomy, frontal sinus trephination and irrigation, frontal sinus drill-out, endoscopic DCR and trans-spehnoidal procedures. Nasopharyngeal/laryngeal procedures would comprise adenoidectomy, laryngeal lesion de-bulking, laryngeal polypectomy, tracheal procedures, and tonsillectomy. Head & neck procedures would encompass soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face, and acoustic neuroma removal. Otology procedures would include mastoidectomy and mastoidotomy.

The Diego Powered Dissector and Drill system that is described in this notification has the same technological characteristics, power modality and mode of operation as the predicate device. The intended uses are substantially equivalent to the described predicate Turbo 7000 System. The Diego Powered Dissector and Drill system is designed to meet *UL 2601-1 including Australian deviations, CSA 22.2 No. 601, IEC 601-1-1 (EN 60601-1), IEC 601-1-2 (EN 60601-1-2), IEC 601-1-4 (EN 60601-1-2), IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 529, ISO 10993-1, EN 55011, Class B.*

The Diego Powered Dissector and Drill System is substantially equivalent to the Turbo 7000 System and difference of the processors that control the units should not affect the safety or effectiveness of the device.

Comparison Chart
Diego Powered Dissector and Drill System
vs.
Turbo 7000 Shaver/Drill System

Console, Footswitch, and Irrigation Pump

	Diego Powered Dissector and Drill System	**Turbo 7000 Shaver Drill System**
Intended Use	General ENT, Head and Neck, and Otoneurologic Procedures	General ENT, Head and Neck, and Otoneurologic Procedures
Driver Configuration	Console with separate footswitch	Console with separate footswitch
Operating Modes	Forward, Reverse, Oscillate	Forward, Reverse, Oscillate
Operating Speeds	Up to 18,000 rpm for sinus surgery and up to 44,000 rpm for otologic, otoneurologic, and acoustic neuroma procedures	Up to 7,000 rpm for sinus surgery and up to 44,000 rpm for otologic, otoneurologic, and acoustic neuroma procedures
Speed Indication	Digital	Digital
Footswitch	Electric	Electric
Irrigation Pump	Yes, integrated into console	Yes, integrated into console
Number of Handpieces supported	4 Diego, Stapes, and Viper Straight and Angled	5 Turbo 7000, Enhanced ESSential Shaver, Stapes, and Viper Straight and Angled
Processor Control	8-bit Microprocessor, Re-programmable (Factory Only)	FPGA (Field Programmable Gate Array) chip, Not re-programmable

Handpieces

	Diego Powered Dissector and Drill System	Turbo 7000 Shaver Drill System
Intended Use	General ENT, Head and Neck, and Otoneurologic Procedures	General ENT, Head and Neck, and Otoneurologic Procedures
Material of Housing	Diego – Stainless Steel Nosecone and Aluminum Housing Viper Handpiece – Stainless Steel Nosecone and Aluminum Housing	Enhanced ESSential Shaver and Stapes – Stainless Steel Viper Handpiece – Stainless Steel Nosecone and Aluminum Housing Turbo 7000 – Aluminum with Stainless Steel Sleeve
Suction Capability	Yes for Shaver Handpiece No for Drill Handpiece	Yes for Shaver Handpiece No for Drill Handpiece
Irrigation Capability	Yes, with the exception of the Stapes Drill Handpiece	Yes, with the exception of the Stapes Drill Handpiece
Chucking Mechanism	Diego is Spring Loaded and able to chuck in multiple positions. The Viper handpieces utilize locking rings and the Stapes uses a collet to secure the burrs	Spring Loaded; ESSential Shaver and Turbo 7000 Shaver Blades/Burrs are able to chuck in multiple positions. The Viper handpieces utilize locking rings and the Stapes uses a collet to secure the burrs
Sterilization Method	Autoclave or EO	Autoclave or EO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Gyrus ENT LLC
c/o Gregory Sredin
Sr. Regulatory Affairs Specialist
2925 Appling Road
Bartlett, TN 38133

Re: K020594
Trade/Device Name: Diego™ Powered Dissector and Drill System
Regulation Number: 21 CFR 874.4250
Regulation Name: ENT Pneumatic or Electric Drill
Regulatory Class: Class II
Product Code: ERL
Dated: February 21, 2002
Received: February 22, 2002

Dear:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K020594

510(k) Number:
Device Name: **Diego™ Powered Dissector and Drill System**

Indications for Use:

The Diego Powered Dissector and Drill System's intended use is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures.

Sinus applications would embody:
- ethmoidectomy/sphenoethmoidectomy
- polypectomy
- septoplasty and
- procedures such as
  - antrostomy
  - endoscopic DCR
  - frontal sinus drill-out
  - frontal sinus trephination and irrigation
  - septal spurs removal
  - trans-spehnoidal procedures

Nasopharyngeal/laryngeal procedures would comprise:
- adenoidectomy
- laryngeal lesion de-bulking
- laryngeal polypectomy
- tracheal procedures
- tonsillectomy

Head & Neck procedures would encompass:
- soft tissue shaving
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid)
- removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face
- acoustic neuroma removal

Otology procedures would include:
- mastoidectomy
- mastoidotomy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Karen Boulware

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K020594